INTRAOCULAR IMPLANT

The present invention relates to an intraocular implant of the "square-edged" type.

Intraocular implants are well known. They are essentially constituted by a substantially circular optical portion and by a haptic portion which serves to hold the optical portion inside the eye in such a manner that the optical axis of the optical portion of the implant coincides with the optical axis of the eye. The free ends of the haptic portion bear against the inside wall of the eye in order to develop a resilient return force ensuring that the implant is held in place.

One of the main uses of such intraocular implants consists in putting the implant in the capsular bag after ablation of the lens during a cataract operation.

It is known that cellular proliferation after cataract surgery is the main post-operative complication of that type of surgery. Such cellular proliferation can cause the posterior portion of the capsular bag to become completely opaque. It is then necessary to perform capsulotomy using an ND-Yag laser.

According to data provided by the literature in this matter, the capsulotomy rate can be as high as 50% within 3 years from the operation, in particular with implants made of rigid material of the PMMA type.

Studies conducted in particular by Nishi et al. which are the subject of a publication in the "Journal of Cataract Refract Surgery", volume 25, April 1999, seem to indicate that it is possible to prevent the cells proliferating on the posterior capsule by means of the edge of the optical portion of the implant acting on the posterior capsule, when the optical portion includes a "square" edge. The term "square edge" has been adopted to define the optical-portion edges having an edge surface which forms an angle of close to 90 degrees (°) relative to the optical surface and which retains a sharp appearance.

In addition, it is known that in intraocular implants, which are now often made in a single piece, the haptic portion is connected to the periphery of the optical portion via a "connection zone". The term "single-piece implant" refers to an implant made as a single piece, even if the optical and the haptic portions are made of different materials. For the implants on which the above-mentioned studies were based, the haptic portion is constituted by two loops of narrow width such that the connection zones constitute a very small percentage only of the entire periphery of the optical portion. Under such circumstances, it will be understood that the square edge of the optical portion is effective in preventing cells from proliferating on the posterior capsule because the square optical edge is interrupted only in zones of very limited length corresponding to the connection zones. However, such zones do allow cells to proliferate.

It will be understood that the problem is even greater where the connection zone(s) represent a significant percentage of the total length of the periphery of the optical portion. In the connection zone(s), proliferation cannot be prevented since the optical portion does not have square edges. Implants having connection zone(s) that represent a significant fraction of the periphery of the optical portion are becoming more and more common, in particular when single-piece implants are made of a flexible material of the "hydrogel" type or of the "silicone" type. That type of connection zone can also be found in implants made of a rigid material, e.g. of the PMMA type, when the haptic contact portion for contact with the inside wall of the eye is constituted substantially by a ring shape connected to the optical portion by a single substantially radial arm having a width that is necessarily relatively great to ensure a suitable

connection between the optical portion and the contact ring of the haptic portion.

It should also be recalled that the surgical practice of putting the implant in place inside the eye is tending to make use of an incision in the cornea that is of smaller and smaller size. When designing intraocular implants, it is therefore necessary to ensure that the overall thickness of the implant remains small so as to enable the implant to be implanted through an incision of small size, with this constraint applying both to the optical portion and to the haptic portion and even to the connection between these two portions. This is particularly, but not exclusively, true of implants having an optical portion that is made of a flexible material enabling the optical portion to be folded on a diameter.

An object of the present invention is to provide an intraocular implant for a capsular bag, the implant being of the square-edged type, thus enabling the proliferation of cells on the posterior capsule to be effectively prevented, in particular in the case where the connection zone(s) for connecting the haptic portion to the optical portion are of significant length, while the thickness of the implant is kept as thin as possible.

To achieve this object, the invention provides an intraocular implant for a capsular bag, which implant comprises an optical portion presenting an anterior optical surface and a posterior optical surface, and at least one haptic element, each haptic element presenting a connection zone at the periphery of the optical portion, said implant being characterized in that:

outside the connection zones, the optical portion further comprises a cylindrical side face of diameter D1 connected to the posterior optical surface of the optical portion and parallel to the optical axis of the implant, the length of the side face along the axis being equal to h;

the posterior optical surface is bounded by a circle of diameter D1;

and in that it further comprises, in each connection zone, a radial extension presenting an anterior face, a posterior face, and a side face substantially disposed on a ruled surface of diameter D2 where D2 > D1, and presenting a length h' in the direction of the axis, said length h' being substantially equal to h;

the posterior face of each extension is disposed on the spherical cap containing the posterior optical surface;

each haptic element being connected to the optical portion via the anterior face of the corresponding extension, on the outside of the anterior optical surface, whereby each extension constitutes a step formed by the offset between the posterior optical surface of the optical portion and the connection zone of the haptic element, the side face of each extension forming a square-edged portion with the posterior optical surface.

It will be understood that because of the presence of radial extension(s) at the connection zone(s), which by means of their side walls constitute respective steps resulting from the offset between the posterior optical surface of the optical portion and the connection zone of the haptic element, continuity of the square edge is obtained over the entire periphery of the optical portion. In addition, the fact that the "root(s)" of the haptic portion(s) is/are connected to the anterior face of the extension(s) prevents any increase in the overall thickness of the implant.

In a preferred implementation, the spherical cap, on which are disposed the posterior optical surface of the optical portion and the posterior faces of the step-forming extensions, has a radius lying in the range 11 millimeters (mm) to 13 mm.

The studies performed for developing the present invention have shown that it is this diameter that

provides the best contact between the posterior capsule and the posterior optical surface of the implant, thus preventing cells from proliferating. This ensures that the posterior capsule, which is very fine, being about 5 microns (μm) thick, is tensioned in the zone defined by contact with the square edge of the implant. The risks of folds forming in the posterior capsule and thus the risks of cells proliferating along said folds are thus avoided.

Also preferably, the haptic portion(s) form(s) an angle $\underline{a}$ lying in the range 5° to 12° relative to the optical plane and directed towards the anterior face of the implant.

This tilt tends to press the posterior optical surface of the implant and the posterior face of the step-forming extensions against the posterior capsule.

Other characteristics and advantages of the invention will appear better on reading the following description of embodiments of the invention given as non-limiting examples. The description refers to the accompanying figures, in which:

Figure 1A is a front view of a first intraocular implant of the invention;

Figure 1B is a side view of the implant of Figure 1A;

Figure 1C is a fragmentary view of Figure 1B showing in more detail the connection between the haptic portion and the optical portion of the implant;

Figure 2A is a front view of a second embodiment of an implant having square edges when viewed from the front; and

Figure 2B is a side view of the implant of Figure 2A.

With reference firstly to Figure 1A, which shows an intraocular implant designed to be placed in the capsular bag, it can be seen that said intraocular implant comprises an optical portion 10 presenting a circular

periphery 10a, and two haptic elements respectively referenced 12 and 14. The haptic elements 12 and 14 are connected to the periphery 10a of the optical portion via connection zones which are indicated by double-headed arrows 16 and 18. It can also be seen that the periphery 10a is free over the remainder of its length, as indicated by double-headed arrows 20 and 22. In these zones, the side wall 10a of the optical portion 10 is substantially cylindrical and is connected to the posterior optical surface in order to form the "square edge", said side wall extending towards the inner optical surface.

As already explained, it is easy to provide a square edge for the free zones of the periphery 20 and 22. The embodiment of the invention which enables a square edge to also be obtained in the connection zones 16 and 18, while preventing any increase in the overall thickness of the implant, is described below in more detail, with reference more particularly to Figures 1B and 1C.

Figure 1B shows the anterior optical surface 24 and the posterior optical surface 26 which define the optical portion 10. The anterior optical surface 24 is constituted by a concave or convex spherical cap and is bounded by a circle of diameter D0 centered on the optical axis XX' of the implant. The posterior optical surface 26 is bounded by a circle of diameter D1 which is preferably greater than D0. The circle of diameter D1 constitutes the physical boundary of the optical portion or optical edge outside the connection zones. The posterior optical surface 26 is convex or plane.

To enable the square edge to be formed in the connection zones 16 and 18, radial extensions 30 and 32 are provided in said connection zones, facing the connection zones, as shown more clearly in Figure 1C. Each extension 30 or 32 comprises an anterior face 30a, a posterior face 30b, and a side face 30c which together constitute a step as described below, thereby, with the

posterior face 30b, constituting the square edge in the connection zone. Furthermore, the posterior face 30b of the extension 30 is disposed on the same spherical cap as the posterior optical surface 26, the spherical cap having a radius R1. The side face 30c of the extension 30 which forms part of the step and the square edge is substantially disposed on a ruled surface of axis XX' and of diameter D2 that is greater than the diameter D1 defining the posterior optical surface 26. The ruled surface can be compared to a cylinder, a cone, a truncated cone, etc. On the portions of its periphery 10a corresponding to the free zones 20 and 22, the optical edge presents a length h in the direction of the axis XX'. In the extension zones 30 and 32, the step constituted by the side wall 30c presents a length h' in the direction of the axis XX', which length is of course slightly shorter than h.

Figure 1C also shows connection of the haptic element 14 to the periphery of the optical portion. Connection of the haptic element 12 is identical. The root 34 of the haptic element 14 is connected to the anterior face 30a of the extension 30, on the outside of the anterior optical surface 24, i.e. on the outside of the circle of diameter D0. Thus, the optical properties of the optical portion are not altered since the roots 34 of the haptic portions are on the outside of the anterior optical surface. Conversely, since the roots are connected to the anterior faces of the extensions 30 and 32, they do not increase the overall thickness of the implant, while making possible the presence of steps 30 and 32 which define the square edges in the connection zones by means of their side faces 30c and their posterior faces 30b.

In a preferred embodiment, the diameter D0 is about 5 mm, the diameter D1 is about 6 mm, and the diameter D2 is about 6.5 mm. The length h' corresponding to the steps in the connection zones is not less than 120 μm and

preferably lies in the range 120 μm to 200 μm. As a result, the optical edge of length h is slightly greater than that value.

The studies performed show that said length h' of the step is sufficient to obtain the desired result, i.e. to prevent cells proliferating on the posterior capsule. Said length h, h' is linked to the size of cells that are capable of proliferating on the posterior capsule.

This result is further improved due to the fact that the radius R1 preferably lies in the range 11 mm to 13 mm, thereby ensuring the best possible contact with the posterior capsule, thus tensioning said capsule and preventing any risk of folds forming. With the radius of the posterior optical surface defined in this way, the power of the implant is determined by appropriately selecting the radius of the anterior optical surface. This is possible for standard optical powers for an implant.

As shown more clearly in Figure 1B, the haptic arms 12 and 14 present, preferably relative to the optical plane PP', an angle of tilt a that lies in the range 5° to 12°. The angle a is preferably close to 10°. In Figure 2B, its value is 9.5°. This tilting of the haptic arms towards the front, tends to press the posterior optical surface, with its extensions, more effectively against the posterior capsule.

In this embodiment, the implant is in a single piece and is made of a flexible material. Each haptic element is constituted by two arms connected together at their contact end. The two arms include a common connection zone.

The implant 50 shown in Figures 2A and 2B differs from the implant in Figures 1A and 1C only in the shape of its haptic portion. The haptic portion is constituted by two haptic assemblies 52 and 54 each formed by two haptic members 56 & 58 and 60 & 62 connected to the periphery of the optical portion 64. In this case, there

are thus four connection zones corresponding to four haptic members. A radial extension is situated in each connection zone, the radial extensions being referenced 66, 68, 70, and 72. The radial extensions 66, 68, 70, and 72 have exactly the same shape as the two radial extensions 30 and 32 in Figures 1A and 1C.

The implant can be made either of a rigid material such as PMMA, or of a flexible material such as silicone or acrylics. For a flexible material, hydrophobic or hydrophilic pHEMA can be used.